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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,836	12/12/2000	Tianci Luo	4-30922A/SYS	4435

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/734,836	LUO ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-13,15-19,23-33 and 40-106* is/are pending in the application.

4a) Of the above claim(s) *8-13,23-33,40-72 and 74-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73 and 80-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,7,8,9* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Applicant's election with traverse of XIV (claims 73 and 80) in Paper No. 14 is acknowledged. Therefore, claims 73 and 81-106 are under consideration in the instant office action.

The traversal is on the ground(s) that the groups are classified in the same class and that neither Group II or group III contain a transgene. This is not found persuasive because the structure of Group II differs from the structure of Group III, therefore, the search for one group will not be coextensive with the other group.

The traversal is on the ground(s) that the claims 71 and 72 should be placed in Group VI instead of Group XII, this is not found persuasive, claims 71 and 72 were placed into the Group XII because they can have the envelope and coding sequences integrated into the genome and thereby do not require a three plasmid construction which is found in Group VI.

The requirement is still deemed proper and is therefore made FINAL.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper Nos. 6, 7, 8 and 9, are attached to the instant Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 73 and 80-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonda (U.S. Pat No. 5,380,830, IDS Paper No 6), in view of Poeschia et al. (WO 99/15641, IDS Paper No. 8) and Temin et al. (U.S. Pat. No. 5,554,524).

The instant invetion is drawn to BIV virion particle, that comprises BIV U5, element a packaging sequence , a transgene and promoter, a 3' polypurine tract and a BIV U3 element.

For this office action, the preamble of the product-by-process claims were interpreted as "a composition of matter" (which are *products*). A composition may be a molecule, compound, solution, mixture, alloy, atom, etc.). Product by process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

Gonda teaches a full-length proviral BIV clone, the reference teaches the similarity between BIV and HIV (see figure 6 and columns 16-18). The reference does not teach constructing a transfer vector, or the production of a recombinant virion particle.

Poeschia et al. teaches the use of non-primate lentiviral vector (feline and ungulate) as a safer alternative than primate lentiviral vectors for the propose of introducing a transgene into a cell. The reference teaches the use of non-primate lentivirus packable nucleic acid, comprising a heterologous target nucleic acid operably linked to a promoter (see page 23 line 25 to page 24, line 28, and figure 1-2). The reference also suggests optionally including a portion of the *env* gene sequence into the packagable nucleic acid. The reference teaches the production of virion particle therefore *gag/pol* and *env* are present in the product. The reference teaches the use of the non-primate gag/pol sequences as well as the use of a VSV-G glycoprotein construct for the envelop. The reference does not specifically mention including the polypurine tract with the

3'UTR (see figure 1-2), however, the reference also does not specifically exclude the polypurine tract from the packagable nucleic acid construct.

Temin et al. teach chimeric retroviral vectors containing the long terminal repeats (LTRs) from complex retroviral (e.g. bovine leukemia virus (BLV); human immunodeficiency virus (HIV)) cis-acting regulatory sequences (e.g. att; primer binding site (PBS); encapsidation site (E), and polypurine tract (ppt)) and coding regions. Cells transfected with these constructs are able to produce retrovirus particles (see figures 4-8, and column 5, lines25-45). The reference does not teach the use of BIV as a source for the packagable nucleic acid construct.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a chimeric retroviral vector for the expression of a transgene using the BIV sequence as taught by Gonda et al. is most similar to HIV. Poeschia et al. provide the motivation of using a non-primate lentiviral construct for the expression of transgene because they would provide a safer source viral particles that can be used to introduce therapeutic nucleic acids constructs into human subjects because there is a reduced risk of recombination to produce an infectious virus. Temin et al. utilize a retroviral construct that has LTR sequences, a packaging sequence and a polypurine tract. Therefore the instant invention is *prima facie* obvious in view of the cited art.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 5/22/03